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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,277	03/25/2002	Dexian Dou	1059.00051	3577

7590 01/18/2005  
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EXAMINER

LANDSMAN, ROBERT S

ART UNIT PAPER NUMBER

1647

DATE MAILED: 01/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/914,277

**Applicant(s)**

DOU ET AL.

**Examiner**

Robert Landsman

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 October 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***1. Formal Matters***

- A. The Amendment dated 10/26/04 has been entered into the record.
- B. Claims 1-4 are pending and are the subject of this Office Action.
- C. All Statutes under 35 USC not found in this Office Action can be found, cited in full, in a previous Office Action.

### ***2. Sequence Compliance***

- A. When a sequence is presented in a drawing, regardless of the format or the manner of presentation of that sequence in the drawing, the sequence must still be included in the Sequence Listing, and a sequence identifier ("SEQ ID NO:X") must be used either in the drawing or in the Brief Description of the Drawings. See MPEP ' 2422.02. In the instant application, a sequence identifier must be used for the sequences appearing in Figures 6 and 24.

Appropriate correction is required.

- B. According to 37 CFR 1.821(d) (MPEP § 2422), where the description or claims of a patent application discuss a sequence listing that is set forth in the "Sequence Listing" in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the assigned identifier, in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application. Sequences appear on pages 104-105; page 98, line 14; page 82, lines 10-30; page 80, line 27 to page 81 line 5; Example 4 of page 53 and throughout pages 40-41 of the specification but are not identified by SEQ ID NO as required.

### ***3. Oath/Declaration***

- A. Applicants have submitted a new Oath. However, it does not appear that a Petition regarding Dr. Dou has been sent to the Office of Petitions. Applicants did not address this issue.

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**4. Specification**

A. The objection to the specification has been withdrawn in view of Applicants' amendment to the title.

B. The objection to the specification has been withdrawn in view of Applicants' submission of a new Figure 5 with recites parts "A" and "B."

**5. Claim Rejections - 35 USC § 112, first paragraph – scope of enablement**

A. Claims 1-4 remain rejected under 35 USC 112, first paragraph, for the reasons already of record on pages 3-4 of the Office Action dated 7/26/04. Applicants argue that the claims have been amended to recite that the proteins have "anti-angiogenic properties" and that these properties have been determined and are useful in treating numerous diseases. These arguments have been considered, but are not deemed persuasive. Applicants have improved the claim language by deleting the phrase "essentially." However, the limitations appear to be inherent properties of kringle, KED and tPA proteins and do not sufficiently limit the scope of the claims. Applicants have not demonstrated that kringles can be used to treat tumors in a patient, nor that all tumors can be treated by KED or kringle proteins, especially in light of the fact that solid tumors and blood-borne tumors such as lymphomas have different characteristics. Applicants have only demonstrated the in vitro effect of a kringle protein in one tumor model. Applicants have not demonstrated that these proteins can be used in vivo. Hence, there is no support for the claim language "a pharmaceutical composition." Furthermore, it is not clear if the tumor model present in the specification is an art-accepted model for the treatment of this, or all possible tumors and tumor types.

Therefore, there remains a lack of guidance and working examples of pharmaceutical compositions comprising all kringle, KED and tPA proteins as well as methods of treating all tumors with these proteins. These factors, along with the lack of predictability to one of ordinary skill in the art as to how treat the scope of tumors encompassed by the claims leads the Examiner to hold that undue experimentation is necessary to practice the invention as claimed.

**6. Claim Rejections - 35 USC § 112, first paragraph – written description**

A. Claims 1-4 remain rejected under 35 USC 112, first paragraph, for the reasons already of record on pages 4-5 of the Office Action dated 7/26/04. Applicants argue that the claims have been amended to recite that the proteins have “anti-angiogenic properties” and that these properties have been determined and are useful in treating numerous diseases. Applicants further argue that kringles are known in the art so it is not necessary for a specific recitation of all the kringles to be recited in the claims. These arguments have been considered, but are not deemed persuasive. Applicants have improved the claim language by deleting the phrase “essentially.” However, the specification provides a written description of only a small number of these kringles (1-5). No other species are described, or structurally contemplated, within the instant specification. Therefore, one skilled in the art cannot reasonably visualize or predict critical amino acid residues which would structurally characterize the genus of kringle proteins, or KED, or tPA claimed, because it is unknown and not described what structurally constitutes any of these different proteins, including those from any different species, which are further not described; thereby not meeting the written description requirement under 35 USC 112, first paragraph.

**7. Claim Rejections - 35 USC § 112, second paragraph**

A. The rejection of claims 2 and 4 under 35 USC 112, second paragraph, has been withdrawn in view of Applicants’ amendments to the claims to remove the phrase “consisting essentially of.”

**8. Claim Rejections - 35 USC § 102**

A. The rejection of claims 1-4 over Henkin et al. has been withdrawn in view of the fact that the filing date of the present invention is earlier than that of the patent.

B. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Gately et al. (PNAS 94 – on the 1449 of 9/11/03). The claims recite pharmaceutical compositions comprising at least one kringle protein and a method of treating a tumor by administering a kringle protein. Gately teach that angiostatin consists of the first 4 or 5 kringle domains of plasminogen and that angiostatic agents such as angiostatin can be used to inhibit tumor growth (Introduction). Angiostatin suppressed Lewis lung carcinoma metastases and inhibited angiogenesis in vitro and in vivo (Abstract). Pharmaceutical compositions were used for this procedure (“Bioactivity of Angiostatin”). The instant claims are not patentable over the

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Gately since the product and process steps of Gately are the same as the present claims regardless of whether it was known in Gately that the kringle domains were the known active factor of angiostatin (Ex parte Novitski, 26 USPQ 1391).

#### ***9. Conclusion***

A. No claim is allowable.

#### ***Advisory information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (571) 272-0888. The examiner can normally be reached on M-Th 9 AM-6 PM (eastern); alt F 9 AM-6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert Landsman  
Primary Examiner  
Art Unit 1647

  
ROBERT LANDSMAN  
PATENT EXAMINER